

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

ELIZABETH BRENSEKE,

Court File No.

Plaintiff,

v.

**COMPLAINT
and DEMAND FOR JURY TRIAL**

MERCK SHARP & DOHME CORP.,

Defendant.

Elizabeth Brenseke (hereinafter “Plaintiff”), by her undersigned counsel, complains against Defendant Merck Sharp & Dohme Corp. (hereafter “Merck” or “Defendant”) based upon her personal knowledge as to her own acts, and upon information and belief, as well as upon her attorneys’ investigative efforts, as to Defendant’s actions and misconduct, alleges as follows:

I. JURISDICTION AND VENUE

1. This court has jurisdiction pursuant to 28 U.S.C. §1332, as complete diversity exists between Plaintiff and Defendant. Plaintiff is a resident of the State of New York and the Defendant is incorporated and has its primary place of business in the State of New Jersey. The amount in controversy, exclusive of interests and costs, exceeds \$75,000.00.

2. Venue in this Court is proper pursuant to 28 U.S.C. § 1391 (a) in that Defendants conduct business in this District and a most substantial part of the events or omissions giving rise to the claims asserted herein occurred in this District.

II. PARTIES

3. Plaintiff was born January 19, 1931. At all relevant times, Plaintiff was a resident of Huntington, New York. Plaintiff used FOSAMAX from approximately January 13, 2005 until September 2008.

4. Defendant is corporation organized and existing under the laws of the State of New Jersey, with its principal place of business in New Jersey. The Defendant's principal office is located at One Merck Drive, Whitehouse Station, New Jersey.

5. Defendant was at all relevant times authorized to conduct business in the State of Minnesota.

6. Defendant has regularly transacted business in the State of Minnesota and continues to do so.

7. At all relevant times, Defendant, through its agents, servants, employees and apparent agents was the designer, manufacturer, marketer, distributor and seller of FOSAMAX, a bisphosphonate drug used primarily to mitigate or reverse the effects of osteoporosis, osteopenia, and Paget's Disease.

8. Defendant, either directly or through its agents, apparent agents, servants or employees, at all relevant times, sold and distributed FOSAMAX in the State of Minnesota.

9. Defendant derives substantial revenue from pharmaceutical products used or consumed in the State of Minnesota.

10. Defendants expected or should have expected that its business activities could or would have consequences within the State of Minnesota.

11. Plaintiff brings this action to recover damages, restitution, refunds and/or for equitable, injunctive and declaratory relief.

12. Defendant placed FOSAMAX into the stream of worldwide commerce and interstate commerce in the United States. It did so without adequate testing and with no warning that the drug carried with it a risk of causing osteonecrosis of the jaw.

III. SUMMARY OF THE CASE

13. Defendant either directly, or through its agents, apparent agents, servants or employees, designed, manufactured, marketed, advertised, distributed and sold FOSAMAX for the treatment of osteoporosis, Paget's Disease, and other uses. As a result of the defective nature of FOSAMAX, persons who were prescribed and ingested FOSAMAX, including Plaintiff, have suffered and continue to suffer severe and permanent personal injuries.

14. Defendant concealed and continues to conceal its knowledge of FOSAMAX's unreasonably dangerous risks from Plaintiff, other consumers, and the medical community.

15. Defendant failed to conduct adequate and sufficient post-marketing surveillance of FOSAMAX after it began marketing, advertising, distributing, and selling the drug.

16. As a result of Defendant's actions and inaction, Plaintiff was injured due to her ingestion of FOSAMAX, which has caused and will continue to cause Plaintiff various injuries and damages. Plaintiff accordingly seeks compensatory damages.

IV. FACTUAL BACKGROUND

17. At all relevant times, Defendant was responsible for, or involved in, designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX.

18. In September 1995, the United States Food and Drug Administration (“FDA”) approved Merck’s compound alendronate for various uses, including the treatment of osteoporosis and Paget’s Disease. Alendronate is marketed by Defendant Merck as FOSAMAX.

19. FOSAMAX falls within a class of drugs known as bisphosphonates. Bisphosphonates are used for treating bone conditions such as osteoporosis and Paget’s Disease. Other drugs within this class, such as Aredia and Zometa, are used as chemotherapy and as adjunct chemotherapy but are not indicated for use in non-cancerous conditions such as osteoporosis.

21. There are two classes of bisphosphonates: the N-containing (nitrogenous) and non-N-containing (non-nitrogenous) bisphosphonates. The nitrogenous bisphosphonates include the following: pamidronate (Aredia); ibandronate (Bondronat); and alendronate (FOSAMAX). The non-nitrogenous bisphosphonates include the following: etridonate (Didronel); clodronate (Bonefos and Loron); and tiludronate (Skelid). Alendronate contains a nitrogen atom. The Physicians Desk Reference (“PDR”) for FOSAMAX confirms that the molecule contains a nitrogen atom.

22. Throughout the 1990s and 2000s, medical articles and studies appeared reporting the frequent and common occurrence of osteonecrosis of the jaw within the nitrogenous bisphosphonates used for chemotherapy. As with its reported and acknowledged side effects concerning irritation, erosion, and inflammation of the upper gastrointestinal tract, Merck knew or should have known that FOSAMAX, as a nitrogenous bisphosphonate, shared a similar adverse event profiles to the other drugs within this specific subclass of bisphosphonates (i.e., those containing nitrogen).

23. Merck knew or should have known that bisphosphonates, including FOSAMAX, inhibit endothelial cell function. Similarly, Merck knew or should have known that Bisphosphonates also inhibit vascularization of the affected area and induce ischemic changes specific to patient's mandibles (lower jaws) and maxillae (upper jaws) and that these ischemic changes appear to be cumulative in nature.

24. Merck also knew or should have known that these factors combine to create a compromised vascular supply in the affected area. As a result, a minor injury or disease can turn into a non-healing wound. That in turn can progress to widespread necrosis (bone death) and osteomyelitis (inflammation of bone marrow).

25. Dentists are now being advised by dental associations to refrain from using any invasive procedure (such as drilling a cavity) for any patient on FOSAMAX.

26. Once the osteonecrosis begins and becomes symptomatic, it is very difficult to treat and typically is not reversible.

27. Shortly after Defendant began selling FOSAMAX, reports of osteonecrosis of the jaw and other dental complications among users began surfacing, indicating that FOSAMAX shared the class effects of the other nitrogenous bisphosphonates. Despite this knowledge, Defendant failed to implement further study of the risk of osteonecrosis of the jaw relative to FOSAMAX. Rather than evaluating and verifying the safety of FOSAMAX with respect to osteonecrosis of the jaw, Defendant proposed further uses of FOSAMAX, such as FOSAMAX-D, and sought to extend the exclusivity period of FOSAMAX through 2018.

28. Osteonecrosis of the jaw is a serious medical event and can result in severe disability and death.

29. Since FOSAMAX was released, the FDA has received a significant number of reports of osteonecrosis of the jaw among users of FOSAMAX.

30. On August 25, 2004, the United States Food and Drug Administration (“FDA”) posted its ODS Postmarketing Safety Review on bisphosphonates – specifically pamidronate (Aredia), zoledronic acid (Zometa), risedronate (Actonel), and alendronate (FOSAMAX). This was an epidemiologic review of the FDA adverse events database conducted by the FDA’s Division of Drug Risk Evaluation.

31. As a result of the FDA Review, the FDA observed that the risk of osteonecrosis of the jaw was not confined to bisphosphonates used for chemotherapy. The FDA’s review indicated that the osteonecrosis of the jaw was a class effect which specifically extended to the oral bisphosphonate, FOSAMAX.

32. As a result, the FDA recommended and stated that the labeling for FOSAMAX should be amended by Defendant to specifically warn about the risk of osteonecrosis of the jaw. Defendant has refused to accede to the FDA’s request and, to this day, still does not warn of the risk of osteonecrosis of the jaw in its FOSAMAX labeling.

33. Rather than warn patients, and despite knowledge known by Defendant about the increased risk of osteonecrosis of the jaw on patient using FOSAMAX, Defendant continues to defend FOSAMAX, mislead physicians and the public, and minimize unfavorable findings.

34. FOSAMAX is one of the Defendant’s top selling drugs, averaging more than \$3 billion a year in sales.

35. Consumers, including Plaintiff, who have used FOSAMAX for treatment or prevention of osteoporosis, have several alternative safer products available to treat or prevent the condition.

36. Defendant knew of the significant risk of dental and oral complications caused by ingestion of FOSAMAX, but Defendant did not adequately and sufficiently warn consumers, including Plaintiff, or the medical community, of such risks.

37. As a direct result, Plaintiff was prescribed FOSAMAX and has been permanently and severely injured, having suffered serious consequences from the ingestion of FOSAMAX. Plaintiff requires and will in the future require ongoing medical care and treatment.

38. Plaintiff has suffered from mental anguish from the knowledge that Plaintiff will have life-long complications as a result of the injuries Plaintiff sustained from the use of FOSAMAX.

39. Plaintiff was prescribed and began taking FOSAMAX on or about January 13, 2005.

40. Plaintiff used FOSAMAX as prescribed and in a foreseeable manner.

41. As a direct and proximate result of using FOSAMAX, Plaintiff suffered severe injury.

42. Plaintiff, as a direct and proximate result of using FOSAMAX, suffered severe mental and physical pain and suffering and has sustained permanent injuries and emotional distress.

43. Plaintiff used FOSAMAX which had been provided to her in a condition that was substantially the same as the condition in which it was manufactured and sold.

44. Plaintiff would not have used FOSAMAX had Defendant properly disclosed the risks associated with the drug. Alternatively, Plaintiff would have known the precursor events of osteonecrosis or osteomyelitis of the jaw and would have been able to avoid the clinical manifestation of the symptoms as they currently exist.

45. Defendant through its affirmative misrepresentations and omissions actively concealed from Plaintiff and her physicians the true and significant risks associated with taking FOSAMAX. The running of any applicable statute of limitations has been tolled by reason of Defendant's fraudulent concealment.

46. As a result of Defendant's actions, Plaintiff and her prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this complaint, and that those risks were the direct and proximate result of Defendant's acts, omissions, and misrepresentations.

COUNTS

COUNT I: NEGLIGENCE

47. Plaintiff restates the allegations set forth above as if fully rewritten herein.

48. Defendant owed Plaintiff and other consumers a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX.

49. Defendants failed to exercise due care under the circumstances and therefore breached this duty by:

- a. failing to properly and thoroughly test FOSAMAX before releasing the drug to the market;
- b. failing to properly and thoroughly analyze the data resulting from the pre-marketing tests of FOSAMAX.
- c. failing to conduct sufficient post-market testing and surveillance of FOSAMAX.
- d. designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX to consumers, including Plaintiff, without an adequate warning of the

significant and dangerous risks of FOSAMAX and without proper instructions to avoid the harm which could foreseeably occur as a result of using the drug;

e. failing to exercise due care when advertising and promoting FOSAMAX; and

f. negligently continuing to manufacture, market, advertise, and distribute

FOSAMAX after Defendant knew or should have known of its adverse effects.

50. As a direct and proximate consequence of Defendant's actions, omissions, and misrepresentations, Plaintiff sustained severe injury. Plaintiff required and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages.

Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

51. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT II: STRICT LIABILITY

52. Plaintiff restates the allegations set forth above as if fully rewritten herein.

53. Defendant manufactured, sold, distributed, marketed, and/or supplied FOSAMAX in a defective and unreasonably dangerous condition to consumers, including Plaintiff.

54. Defendant designed, manufactured, sold, distributed, supplied, marketed, and/or promoted FOSAMAX, which was expected to reach and did in fact reach consumers, including

Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendant.

55. Plaintiff used FOSAMAX as prescribed and in a manner normally intended, recommended, promoted, and marketed by Defendant.

56. FOSAMAX failed to perform safely when used by ordinary consumers, including Plaintiff, as intended and in a reasonably foreseeable manner.

57. FOSAMAX was defective in its design and was unreasonably dangerous in that it unforeseeable risks exceeded the benefits associated with its design or formulation.

58. FOSAMAX was defective in design and formulation in that it posed a greater likelihood of injury than other similar medications and was more dangerous than an ordinary consumer could reasonably foresee or anticipate.

59. FOSAMAX was defective in its design and was unreasonably dangerous in that it neither bore nor was packaged with nor accompanied by warnings adequate to alert consumers, including Plaintiff, of the risks described herein, including, but not limited to, the risk of osteonecrosis and osteomyelitis of the jaw.

60. Although Defendant knew or should have known of the defective nature of FOSAMAX, it continued to design, manufacture, market, and sell FOSAMAX so as to maximize sales and profits at the expense of public health and safety. By so acting, Defendant acted with conscious and deliberate disregard of the foreseeable harm caused by FOSAMAX.

61. Plaintiff could not through the exercise of reasonable care have discovered FOSAMAX's defects or perceived the dangers posed by the drug.

62. As a direct and proximate result of Defendant's conduct, Plaintiff sustained severe injury. Plaintiff required and will continue to require healthcare and services. Plaintiff has

incurred and will continue to incur medical and related expenses. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

63. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT III: BREACH OF EXPRESS WARRANTY

64. Plaintiff restates the allegations as set forth above as if fully rewritten herein.

65. Defendant expressly represented to Plaintiff and other consumers and the medical community that FOSAMAX was safe and fit for its intended purposes, and that it was of merchantable quality, that it did not produce any dangerous side effects, and that it was adequately tested.

66. FOSAMAX does not conform to Defendant's express representations because it is not safe, has numerous and serious side effects, and causes severe and permanent injuries.

67. At all relevant times, FOSAMAX did not perform as safely as an ordinary consumer would expect when used as intended or in a reasonably foreseeable manner.

68. Plaintiff, other consumers, and the medical community reasonably relied upon Defendant's express warranties.

69. As a direct and proximate result of Defendant's actions, Plaintiff sustained severe injury. Plaintiff required and will continue to require healthcare and services. Plaintiff has

incurred and will continue to incur medical and related expenses. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, and activation of latent conditions, and other losses and damages. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

70. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT IV: BREACH OF IMPLIED WARRANTY

71. Plaintiff restates the allegations set forth above as if fully rewritten herein.

72. Defendant manufactured, distributed, advertised, promoted, and sold FOSAMAX.

73. At all relevant times, Defendant knew of the use for which FOSAMAX was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

74. Defendant was aware that consumers, including Plaintiff, would use FOSAMAX for the treatment of osteoporosis and for other purposes.

75. Plaintiff and the medical community reasonably relied upon the judgment and sensibility of Defendant to sell FOSAMAX only if it was indeed of merchantable quality and safe and fit for its intended use.

76. Defendant breached its implied warranty to consumers, including Plaintiff, because FOSAMAX was not of merchantable quality and not safe and fit for its intended use.

77. Consumers, including Plaintiff, reasonably relied upon Defendant's implied warranty for FOSAMAX.

78. FOSAMAX reached consumers without substantial change in the condition in which it was manufactured and sold by Defendant.

79. As a direct and proximate result of Defendant's actions, Plaintiff sustained severe injury. Plaintiff required and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, and activation of latent conditions, and other losses and damages. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

80. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT V: FRAUDULENT MISREPRESENTATION

81. Plaintiff restates the allegations set forth above as if fully rewritten herein.

82. Defendant made fraudulent misrepresentations with respect to FOSAMAX in the following particulars:

- a. Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that FOSAMAX had been tested and found to be safe and effective for the treatment of and prevention of osteoporosis; and

- b. Defendant represented that FOSAMAX was safer than other alternative medications.

83. Defendant knew that its representations were false, yet it willfully, wantonly, and recklessly disregarded its obligation to provide truthful representations regarding the safety and risk of FOSAMAX to consumers, including plaintiff, and the medical community.

84. The representations were made by Defendant with the intent that doctors and patients, including Plaintiff, rely upon them.

85. Defendant's misrepresentations were made with the intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to induce and encourage the sale of FOSAMAX.

86. Plaintiff's doctors, Plaintiff, and others relied upon the representations.

87. Defendant's fraudulent representations evinced its callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff.

88. As a direct and proximate result, Plaintiff sustained severe injury. Plaintiff required and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, and activation of latent conditions, and other losses and damages. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

89. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of

consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT VI: FRAUDULENT CONCEALMENT

90. Plaintiff restates the allegations set forth as if fully rewritten herein.

91. Defendant fraudulently concealed information with respect to FOSAMAX in the following particulars:

- a. Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that FOSAMAX was safe and fraudulently withheld and concealed information about the substantial risks of using FOSAMAX; and
- b. Defendant represented that FOSAMAX was safer than other alternative medications and fraudulently concealed information which demonstrated that FOSAMAX was not safer than alternatives on the market.

92. Defendant had sole access to the material facts concerning the dangers and unreasonable risk of FOSAMAX.

93. The concealment of information by Defendant about the risks of FOSAMAX was intentional, and the representations made by Defendant were known by Defendant to be false.

94. The concealment of information and the misrepresentations about FOSAMAX were made by Defendant with the intent that doctors and patients, including Plaintiff, rely upon them.

95. Plaintiff's doctors, Plaintiff, and others, relied upon the representations and were unaware of the substantial dental and oral risks of FOSAMAX which Defendant concealed from Plaintiff's doctors and Plaintiff.

96. As a direct and proximate result of Defendant's fraudulent concealment and misrepresentation, Plaintiff sustained severe and permanent injuries, including pain and mental and physical anguish and suffering, including a diminished capacity for the enjoyment of life, aggravation of preexisting conditions and activation of latent conditions, and a fear of developing other harmful conditions or problems as a result of injury. Plaintiff has also incurred expense for medical care and treatment due to the injuries caused by FOSAMAX.

97. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

**COUNT VII: VIOLATION OF THE FALSE ADVERTISING ACT,
THE CONSUMER FRAUD ACT, THE UNLAWFUL TRADE PRACTICES ACT,
AND THE UNIFORM DECEPTIVE TRADE PRACTICES ACT**

98. Plaintiff restates the allegations set forth as if fully rewritten herein.

99. By reason of the conduct as alleged herein, and by inducing Plaintiff and Plaintiff's physician to use FOSAMAX through the use of false and misleading advertising, representations, and statements, Defendants violated the provisions of Minn. Stat. §§ 325F.67, 325F.69, 325D.13, and 325D.44.

100. As a direct and proximate result of Defendant's statutory violations, Plaintiff and Plaintiff's physician were induced to use FOSAMAX and plaintiff suffered injury, which would not have occurred had Defendant not issued false or misleading advertising, representations, and statements to induce Plaintiff and Plaintiff's physicians to use the product.

101. By reason of such violations and pursuant to Minn. Stat. § 8.31, subd. 3a, § 325D.44, § 325F.67, and §§ 325F.68-70, Plaintiff is entitled to recover all of the monies paid for FOSAMAX; to be compensated for the cost of the medical care arising out of the use of FOSAMAX; and all consequential damages recoverable under the law including, without restriction, both past and future medical expenses, past wage loss, loss of future earning capacity, past and future pain, suffering, disability, and emotional distress.

102. Additionally, pursuant to Minn. Stat. § 8.31, because Defendants' wrongful acts were directed not just at Plaintiff, but at the public in general, and represented conduct against which the public in general has a direct interest in protecting, Plaintiff is entitled to recover costs and disbursements, including costs of investigation and reasonable attorney's fees, and any other equitable relief as deemed appropriate by this Court.

COUNT VIII: PUNITIVE DAMAGES

103. Plaintiff restates the allegations set forth above as if fully rewritten herein.

104. Defendant has repeatedly engaged in a pattern of conduct of deliberately avoiding FDA recommendations as to which warnings relating to public hazards should be warned about.

105. For example, in March 2000, Defendant completed a study called VIGOR (VIOXX Gastrointestinal Outcomes Research) relating to its prescription cox-2 inhibitor, VIOXX. The VIGOR study show that VIOXX patients had more than double the rate of serious cardiovascular problems than those on Naproxen, an older non-steroidal anti-inflammatory drug. The study was published in the New England Journal of Medicine.

106. In September 2001, the FDA warned Defendant to stop misleading doctors about VIOXX's effect on the cardiovascular system. Defendant Merck was admonished to stop

minimizing the risks of the drug in its marketing. Despite that, Defendant refused to adequately warn physicians and patients about the risk of heart attacks and VIOXX.

107. On August 25, 2004, a representative from the FDA presented results of a database analysis of 1.4 million patients. The analysis demonstrated that VIOXX users were more likely to suffer a heart attack or sudden cardiac death than those taking older non-steroidal drugs. The FDA representative concluded that VIOXX was linked to more than 27,000 heart attacks or sudden cardiac deaths nationwide from the time it came on the market in 1999 through 2003.

108. On August 26, 2004, Defendant released a press statement which refuted the FDA analysis and restated the Defendant's support for the cardiovascular safety of VIOXX.

109. On September 30, 2004, Defendant recalled VIOXX from the market, after having to halt the APPROVe study (Adenomatous Polyp Prevention on Vioxx). The study was underway to evaluate the use of VIOXX for recurrent colon polyps. The researchers found an alarming number of cardiovascular events among the drug's users in the APPROVe study.

110. At the same time, Defendant was aware that the FDA, as of August 24, 2004, was advising Defendant to warn about the risk of osteonecrosis of the jaw for its FOSAMAX patients. Because Defendant knew that its blockbuster drug VIOXX was about to be pulled from the market, placing more importance on the \$3 billion+ annual sales of FOSAMAX, Defendant deliberately chose to not amend its packaging of FOSAMAX to include the risk of osteonecrosis of the jaw, fearing that such a warning would result in reduced revenues for its second largest income producer, FOSAMAX.

111. Defendant's acts were willful and malicious in that Defendant's conduct was carried on with a conscious disregard for safety and rights of Plaintiff and other consumers.

Defendant's unconscionable conduct thereby warrants an assessment of exemplary and punitive damages against Defendant in an amount appropriate to punish Defendant, and deter similar conduct in the future.

DEMAND FOR JURY TRIAL

Plaintiff demands a jury trial as to all claims that may be tried in this action.

RELIEF SOUGHT

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, for damages, as well as all costs of this action, to the fullest extent of the law including:

- A. For general damages in an amount to be proven at trial;
- B. For special damages in an amount to be proven at trial;
- C. For exemplary and punitive damages in an amount to be proven at the time of trial, and sufficient to punish Defendant or to deter Defendant and others from repeating the injurious conduct alleged herein;
- D. For pre-judgment and post-judgment interest on the above general and special damages; and
- E. For costs of this suit and attorney fees; and
- F. For all other relief that Plaintiff, may be entitled to at equity or at law.

Dated: July 2, 2010

LAW OFFICES OF CHARLES H. JOHNSON, PA

/s/ Charles H. Johnson

Charles H. Johnson, Esq. (#50696)

Jonathan R. Mencil, Esq. (#390056)

Attorneys for Plaintiff

2599 Mississippi Street

New Brighton, MN 55112-5060

Telephone: (651) 633-5685

Fax Phone: (651) 633-4442